

September 25, 2006

TFW

PATENT APPLICATION
DOCKET NO.: 3022.1004-000

1645

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Joerg Schneider, Sarah C. Gilbert, Carolyn M. Hannan and Adrian V.S. Hill

Application No.: 10/088,677 Group Art Unit: 1645

371(c) Date: May 31, 2002 Examiner: Robert A. Zeman

Confirmation No.: 4825

Title: USE OF REPLICATION-DEFICIENT ADENOVIRAL VECTOR TO BOOST
CD8+ T CELL IMMUNE RESPONSE TO ANTIGEN

CERTIFICATE OF MAILING OR TRANSMISSION

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, or is being facsimile transmitted to the United States Patent and Trademark Office on:

September 26, 2006

Date

Marianne Lentini

Signature

MARIANNE LENTINI

Typed or printed name of person signing certificate

FOURTH SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Fourth Supplemental Information Disclosure Statement is submitted:

☐ under 37 CFR 1.129(a), or

(First/Second submission after Final Rejection)

☐ under 37 CFR 1.97(b), or

(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).

☒ under 37 CFR 1.97(c) together with either:

☐ a Statement under 37 CFR 1.97(e), as checked below, or

☒ a \$180.00 fee under 37 CFR 1.17(p), or

(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)

☐ under 37 CFR 1.97(d) together with:

☐ a Statement under 37 CFR 1.97(e), as checked below, and

☐ a \$180.00 fee under 37 CFR 1.17(p), or

(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)

☐ under 37 CFR 1.97(i):

Applicant requests that the IDS and cited reference(s) be placed in the application file.

(Filed after payment of issue fee)

09/29/2006 RHEBRIGHT 00000072 10088677

180.00 OP

01 FC:1806

Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.
- ☒ Enclosed herewith is form PTO-1449:
 - ☒ Copies of the cited references, B12, B13 and C146-C185, are enclosed.
 - ☒ Copies of issued U.S. patents and published U.S. applications are not required and are not being provided.
 - ☐ Copies of the cited references are enclosed except those entered in prior application, U.S. Application No. [], to which priority under 35 U.S.C. 120 is claimed. [The earlier application contains copies of the cited references.]
 - ☐ The listed references were cited in the enclosed International Search Report in a counterpart foreign application.
 - ☐ The "concise explanation" requirement (non-English references) for reference(s) [] under 37 CFR 1.98(a)(3) is satisfied by:
 - ☐ the explanation provided on the attached sheet.
 - ☐ the explanation provided in the Specification.
 - ☐ submission of the enclosed International Search Report.
 - ☐ submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.
 - ☐ the enclosed English language abstract.

- ☐ Applicant requests that the following non-published pending applications be considered:
(Affix a label or apply the stamp "Non-Published IDS Reference - Do Not Scan" to the front of each unpublished pending appl'n.)

Examiner's
Initials

____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []
____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []
____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []

Examiner

Date

- ☐ A copy of each above-cited application, including the current claims, is enclosed, except any application filed on or after June 30, 2003, which has been scanned into the PTO's Image File Wrapper (IFW) system and is available to the examiner.
- ☐ A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

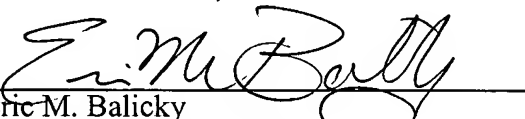
It is requested that the information disclosed herein be made of record in this application.

Method of payment:

- ☒ A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.
- ☐ Please charge Deposit Account 08-0380 in the amount of \$[]. A copy of this Statement is enclosed.
- ☒ Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

By 

Eric M. Balicky
Registration No.: 57,020
Telephone: (978) 341-0036
Facsimile: (978) 341-0136

Concord, MA 01742-9133

Dated:

September 26, 2006

APPLICATION NO.
10/088,677

**FOURTH SUPPLEMENTAL
INFORMATION DISCLOSURE STATEMENT
IN AN APPLICATION**

September 26, 2006

(Use several sheets if necessary)

FIRST NAMED INVENTOR
Joerg Schneider

371(C) DATE
May 31, 2002

EXAMINER
Robert A. Zeman

CONFIRMATION NO.
4825

GROUP
1645

U.S. PATENT DOCUMENTS

[illegible]

EXAMINER

DATE CONSIDERED

[illegible]

EXAMINER	DATE CONSIDERED
----------	-----------------

PTO-1449 REPRODUCED FOURTH SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION September 26, 2006 (Use several sheets if necessary)	ATTORNEY DOCKET NO. 3022.1004-000		APPLICATION NO. 10/088,677	
	FIRST NAMED INVENTOR Joerg Schneider		371(C) DATE May 31, 2002	
	EXAMINER Robert A. Zeman	CONFIRMATION NO. 4825	GROUP 1645	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)	
C146	Ahlers, J.D., <i>et al.</i> , "Cytokine-in-Adjuvant Steering of the Immune Response Phenotype to HIV-1 Vaccine Constructs," <i>J. Immunol.</i> 158(8):3947-3958 (1997).
C147	Allen, T.M. and Watkins, D.I., SIV and SHIV CTL Epitopes Identified in Macaques [online], December 1998. Retrieved from the Internet <URL:http://hiv-web.lanl.gov/content/hiv-db/COMPENDIUM/1998/III/Allen98.pdf>.
C148	An, L.-L., and Whitton, J.L., "A Multivalent Minigene Vaccine, Containing B-Cell, Cytotoxic T-Lymphocyte, and T _h Epitopes from Several Microbes, Induces Appropriate Responses In Vivo and Confers Protection against More than One Pathogen," <i>J. Virol.</i> 71(3): 2292-2302 (1997).
C149	Austyn, J.M. and Wood, K.J., "An Overview of Immune Responses," In <i>Principles of Cellular and Molecular Immunology</i> , (NY: Oxford University Press Inc.), pp. 42-44 (1993).
C150	Bakker, A.B.H., <i>et al.</i> , "Identification of a Novel Peptide Derived from the Melanocyte-Specific GP100 Antigen as the Dominant Epitope Recognized by an HLA-A2.1-Restricted Anti-Melanoma CTL Line," <i>Int. J. Cancer</i> , 62: 97-102 (1995).
C151	Bergmann, C.C., <i>et al.</i> , "Flanking Residues Alter Antigenicity and Immunogenicity of Multi-Unit CTL Epitopes," <i>J. Immunol.</i> 157(8): 3242-3249 (1996).
C152	Bukowski, J.F., <i>et al.</i> , "Natural Killer Cell Depletion Enhances Virus Synthesis and Virus-Induced Hepatitis <i>In Vivo</i> ," <i>J. Immunol.</i> 131(3): 1531-1538 (1983).
C153	Casares, N., <i>et al.</i> , "CD4 ⁺ /CD25 ⁺ Regulatory Cells Inhibit Activation of Tumor-Primed CD4 ⁺ T Cells with IFN- γ -Dependent Antiangiogenic Activity, as well as Long-Lasting Tumor Immunity Elicited by Peptide Vaccination," <i>J. Immunol.</i> 171(11): 5931-5939 (2003).
C154	Cox, W.I., <i>et al.</i> , "Induction of Cytotoxic T Lymphocytes by Recombinant Canarypox (ALVAC) and Attenuated Vaccinia (NYVAC) Viruses Expressing the HIV-1 Envelope Glycoprotein," <i>Virology</i> , 195: 845-850 (1993).
C155	Egan, M.A., <i>et al.</i> , "Use of Major Histocompatibility Complex Class I/Peptide/ β 2M Tetramers To Quantitate CD8 ⁺ Cytotoxic T Lymphocytes Specific for Dominant and Nondominant Viral Epitopes in Simian-Human Immunodeficiency Virus-Infected Rhesus Monkeys," <i>J. Virol.</i> 73(7): 5466-5472 (1999).
C156	Eisenlohr, L.C., <i>et al.</i> , "Flanking Sequences Influence the Presentation of an Endogenously Synthesized Peptide to Cytotoxic T Lymphocytes," <i>J. Exp. Med.</i> 175: 481-487 (1992).

EXAMINER	DATE CONSIDERED
----------	-----------------

PTO-1449 REPRODUCED FOURTH SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION September 26, 2006 (Use several sheets if necessary)	ATTORNEY DOCKET NO. 3022.1004-000		APPLICATION NO. 10/088,677	
	FIRST NAMED INVENTOR Joerg Schneider		371(C) DATE May 31, 2002	
	EXAMINER Robert A. Zeman	CONFIRMATION NO. 4825	GROUP 1645	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
C157	Feng, C.G., <i>et al.</i> , "Induction of CD8 ⁺ T-lymphocyte Responses to a Secreted Antigen of <i>Mycobacterium tuberculosis</i> by an Attenuated Vaccinia Virus," <i>Immunol. Cell Biol.</i> 79: 569-575 (2001).	
C158	Gherardi, M.M., <i>et al.</i> , "Prime Boost Immunization Schedules Based on Influenza Virus and Vaccinia Virus Vectors Potentiate Cellular Immune Responses Against Human Immunodeficiency Virus Env Protein Systemically and in the Genitoretal Draining Lymph Nodes," <i>J. Virol.</i> 77(12): 7048-7057 (2003).	
C159	Gilbert, S.C., <i>et al.</i> , "DNA Immunisation of Mice with <i>Plasmodium berghei</i> Antigens: Use of Whole Antigens or Multi-epitope Strings, Boosting with Vaccinia and Protection Against Challenge," <i>Immunol. Lett.</i> , 56/1-3: 28 (1997) (Abstract No. 0.4.05.7).	
C160	Gönczöl, E., <i>et al.</i> , "Preclinical Evaluation of an ALVAC (canarypox)-human Cytomegalovirus Glycoprotein B Vaccine Candidate," <i>Vaccine</i> , 13(12): 1080-1085 (1995).	
C161	Hanke, T., <i>et al.</i> , "DNA and MVA-based Multi-CTL Epitope Vaccines for HIV and <i>Plasmodium falciparum</i> : Immunogenicity in Mice and Macaques," <i>Immunol. Lett.</i> , 56/1-3: 291 (1997) (Abstract No. P.4.01.22).	
C162	Hu, S.-L., <i>et al.</i> , "Protection of Macaques Against SIV Infection by Subunit Vaccines of SIV Envelope Glycoprotein gp160," <i>Science</i> , 255: 456-459 (1992).	
C163	Hunter, C.A., "How are NK Cell Responses Regulated During Infection?," <i>Experimental Parasitology</i> , 84: 444-448 (1996).	
C164	Janeway, C.A., <i>et al.</i> , "General Properties of Armed Effector T Cells." In <i>Immuno Biology</i> , (NY: Garland Publishing) p. 319 (2001).	
C165	Konishi, E., <i>et al.</i> , "Induction of Japanese Encephalitis Virus-specific Cytotoxic T Lymphocytes in Humans by Poxvirus-based JE Vaccine Candidates," <i>Vaccine</i> , 16(8): 842-849 (1998).	
C166	Konishi, E., <i>et al.</i> , "Poxvirus-Based Japanese Encephalitis Vaccine Candidates Induce JE Virus-Specific CD8 ⁺ Cytotoxic T Lymphocytes in Mice," <i>Virology</i> , 227: 353-360 (1997).	
C167	Kuby, J., "Cell-Mediated and Humoral Effector Responses." In <i>Immunology</i> , (NY: W. H. Freeman and Company) pp. 379-412 (1997).	
C168	Linnemeyer, P.A., The Immune System - An Overview [online] November 1993 [retrieved on 2006-04-12]. Retrieved from the Internet <URL:http://www.thebody.com/step/immune.html>.	

EXAMINER	DATE CONSIDERED
----------	-----------------

PTO-1449 REPRODUCED FOURTH SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION September 26, 2006 (Use several sheets if necessary)	ATTORNEY DOCKET NO. 3022.1004-000		APPLICATION NO. 10/088,677	
	FIRST NAMED INVENTOR Joerg Schneider		371(C) DATE May 31, 2002	
	EXAMINER Robert A. Zeman	CONFIRMATION NO. 4825	GROUP 1645	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
C169	Malcherek, G., <i>et al.</i> , "Supermotifs Enable Natural Invariant Chain-derived Peptides to Interact with Many Major Histocompatibility Complex-Class II Molecules," <i>J. Exp. Med.</i> 181: 527-536 (1995).	
C170	Martin, R.M. and Lew, A.M., "Is IgG2a a Good Th1 Marker in Mice?" <i>Immunol. Today</i> 19:49 (1998).	
C171	Müller, H.M., <i>et al.</i> , "Thrombospondin Related Anonymous Protein (TRAP) of <i>Plasmodium Falciparum</i> in Parasite-Host Cell Interactions," <i>Parassitologia</i> 35(Suppl.): 69-72 (1993).	
C172	Narvaiza, I., <i>et al.</i> , Intratumoral Coinjection of Two Adenoviruses, One Encoding the Chemokine IFN- γ -Inducible Protein-10 and Another Encoding IL-12, Results in Marked Antitumoral Synergy," <i>J. Immunol.</i> 164(6): 3112-3122 (2000).	
C173	Ojcius, D. M., <i>et al.</i> , "Is Antigen Processing Guided by Major Histocompatibility Complex Molecules?," <i>FASEB J.</i> , 8: 974-978 (1994).	
C174	Okuda, K., <i>et al.</i> , "Induction of Potent Humoral and Cell-Mediated Immune Responses Following Direct Injection of DNA Encoding the HIV Type 1 <i>env</i> and <i>rev</i> Gene Products," <i>Aids Res. Hum. Retroviruses</i> 11(8): 933-943 (1995).	
C175	Plebanski, M., <i>et al.</i> , "Protection from <i>Plasmodium berghei</i> Infection by Priming to a Single CTL Epitope with Vaccine Carriers that do not Require Adjuvants," <i>Immunol. Lett.</i> , 56/1-3: 425 (1997) (Abstract No. P.4.05.08).	
C176	Ramirez, J.C., <i>et al.</i> , "Biology of Attenuated Modified Vaccinia Virus Ankara Recombinant Vector in Mice: Virus Fate and Activation of B- and T-Cell Immune Responses in Comparison with the Western Reserve Strain and Advantages as a Vaccine," <i>J. Virol.</i> 74(2): 923-933 (2000).	
C177	Reusser, P., <i>et al.</i> , "Cytomegalovirus-Specific T-Cell Immunity in Recipients of Autologous Peripheral Blood Stem Cell or Bone Marrow Transplants," <i>Blood</i> , 89(10): 3873-3879 (1997).	
C178	Romero, P., <i>et al.</i> , "Cloned Cytotoxic T Cells Recognize an Epitope in the Circumsporozoite Protein and Protect Against Malaria," <i>Nature</i> , 341: 323-326 (1989).	
C179	Schneider, J., <i>et al.</i> , "DNA Followed by Recombinant Vaccinia Induces Cellular and Humoral Immune Responses Against a Pre-erythrocytic Antigen of <i>Plasmodium falciparum</i> in Chimpanzees," <i>Immunol. Lett.</i> , 56/1-3: 291 (1997) (Abstract No. P.4.01.18).	

EXAMINER	DATE CONSIDERED
----------	-----------------

PTO-1449 REPRODUCED FOURTH SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION September 26, 2006 (Use several sheets if necessary)	ATTORNEY DOCKET NO. 3022.1004-000		APPLICATION NO. 10/088,677	
	FIRST NAMED INVENTOR Joerg Schneider		371(C) DATE May 31, 2002	
	EXAMINER Robert A. Zeman	CONFIRMATION NO. 4825	GROUP 1645	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
C180	Takada, K., <i>et al.</i> , "Definition of an Epitope on Japanese Encephalitis Virus (JEV) Envelope Protein Recognized by JEV-specific Murine CD8+ Cytotoxic T Lymphocytes," <i>Arch. Virol.</i> , 145: 523-534 (2000).	
C181	Vasmatzis, G., <i>et al.</i> , "Computational Determination of Side Chain Specificity for Pockets in Class I MHC Molecules," <i>Mol. Immunol.</i> 33(16): 1231-1239 (1996).	
C182	Whitton, J.L., <i>et al.</i> , "A "String-of-Beads" Vaccine, Comprising Linked Minigenes, Confers Protection from Lethal-Dose Virus Challenge," <i>J. Virol.</i> 67(1): 348-352 (1993).	
C183	Yang, Y., <i>et al.</i> , "Upregulation of Class I Major Histocompatibility Complex Antigens by Interferon γ is Necessary for T-cell-mediated Elimination of Recombinant Adenovirus-infected Hepatocytes <i>In Vivo</i> ," <i>Proc. Natl. Acad. Sci. USA</i> , 92: 7257-7261 (1995).	
C184	Yellen-Shaw, A.J., <i>et al.</i> , "Point Mutation Flanking a CTL Epitope Ablates In Vitro and In Vivo Recognition of a Full-Length Viral Protein," <i>J. Immunol.</i> 158(7): 3227-3234 (1997).	
C185	Zhu, M., <i>et al.</i> , "Specific Cytotoxic T-Cell Responses to Human CEA from Patients Immunized with Recombinant Avipox-CEA Vaccine," <i>Clin. Cancer Res.</i> 6: 24-33 (2000).	

EXAMINER	DATE CONSIDERED
----------	-----------------